

## **REMARKS**

### **I. Introduction**

In response to the pending Office Action, Applicants have incorporated the limitations of claims 2-3 into claim 1. In addition, claims 4-6, 8-10, 14, 17-18, 21-23, 26-29, 32-35 and 38-43 have been amended to overcome the § 112 and 101 rejection. Specifically, the word "or" in claim 2 has been replaced by "of", which has been incorporated into claim 1. The recitation of tethanolamine in claims 8, 9, 26-29 and 32-35 has been corrected to triethanolamine as set out in the tables on pages 4 and 5. In claims 10 and 38-43 the word "user" has been amended to "use". In order to correct the antecedents in the claims, the word "composition" in claims 4, 5, 6, 14, 17 and 18 has been replaced with the word "formulation". In claims 5 and 14, the content of triethanolamine has been amended from "0.1 to 0.06%" to "0.01 to 0.06%", which amendment finds basis on page 3 lines 23-24 of the application as filed. Periods have been added to the end of claims 8, 9, 26-29 and 32-35. Furthermore, claims 2-3, 11-13, 15-16, 19-20, 24-25, 30-31 and 36-37 have been cancelled, without prejudice. No new matter has been added.

With regard to the term "light liquid paraffin", Applicants submit that this term is defined on page 316 in the Handbook of Pharmaceutical Excipients (2nd Ed.) as an alternative name for light mineral oil, which is a mixture of refined liquid saturated hydrocarbons obtained from petroleum. The term "light" means that the substance is less viscous and has a lower specific gravity than mineral oil. Accordingly, Applicants submit that the term "light liquid paraffin" is clearly defined.

Applicants respectfully submit that all pending claims are patentable over the cited prior art for the reasons set forth below.

**II. The Rejection Of Claims 1-34 Under 35 U.S.C. § 102/103**

Claims 1, 5, 7 and 21 were rejected under 35 U.S.C. § 102(b) as being anticipated by Blum et al. (USP No. 5,885,600). Also, claims 1, 2, 5, 7, 19 and 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by, or in the alternative, rejected under 35 U.S.C. § 103(a) as being unpatentable over Marenick et al. (US 2005/0105005). In addition, claims 1-9 and 11-35 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Marenick in view of Vroman (WO 01/85112). As the limitations of claims 2 and 3 have been incorporated into claim 1, the rejection under 35 U.S.C. § 102 over Blum and under 35 U.S.C. § 103(a) over Marenick are rendered moot. In addition, as claims 11-13, 15-16, 19-20, 24-25, 30-31 and 36-37 have been cancelled, these rejections are moot. Accordingly, the § 103 rejection over Marenick in view of Vroman is the sole remaining rejection currently applicable to the pending claims. Applicants respectfully traverse these rejections of the pending claims for at least the following reasons.

With regard to the present disclosure, amended independent claim 1 recites a pharmaceutical formulation for use in repelling and/or killing human head lice comprising a solution of Neem Oil and a surfactant, wherein the solution comprises from about 1% w/w to about 1.25% w/w of Neem Oil and from about 0.2% to about 0.3% w/w of surfactant, and the surfactant is cetrimonium chloride.

One feature of the present disclosure is that the pharmaceutical composition is used for treating human head lice with a solution comprising Neem oil and cetrimonium chloride.

In contrast to the present disclosure, Marenick et al does not disclose the use of cetrimonium chloride as a surfactant in the compositions described in that document. Rather, Marenick et al is directed to the formulation of compositions which may reduce cellulite, assist with reducing muscle soreness, or assist with healing. Thus, Marenick is silent with regard to the treatment of head lice infestation, and silent with regard to using cetrimonium chloride. As such, one skilled in the art wishing to improve the treatment of head lice infestation according to the present disclosure would not refer to Marenick. If a skilled artisan did refer to Marenick, he would find no motivation to use neem oil in particular as selected from the very large number of essential oils recited in that document to which no specific functions are ascribed. None of the examples of Marenick use neem oil. Further, as Marenick does not disclose the use of cetrimonium chloride as surfactant in the compositions described therein, and as neem oil is not referred to for treating lice, there is no motivation to a skilled artisan reading Marenick to arrive at claim 1 of the present disclosure. Accordingly, it is clear that Marenick fails to disclose amended claim 1.

Moreover, Vroman fails to remedy this deficiency. It is alleged that it would be obvious to the skilled man to modify the compositions disclosed in Marenick in order to provide repellency by adding the cetrimonium chloride disclosed in Vroman. However, as noted above the disclosure of Marenick is directed to providing compositions which may reduce cellulite, assist with reducing muscle soreness, or assist with healing.

There is no disclosure in Marenick that the compositions therein may be used as insect repellents or insecticides. Likewise, Vroman is directed to providing an improved shaving foam, and does not disclose that the compositions therein have any insect repellent or insecticidal activity. Thus, the Examiner has provided no teaching or suggestion as to why a skilled artisan seeking to provide an insect repellent or insecticidal composition would refer to either Marenick or Vroman to arrive at such a composition as described in the present disclosure. Neither Marenick nor Vroman teach anything regarding insect repellency or insecticidal activity.

Furthermore, the disclosures of Marenick and Vroman are in completely different fields from one another, and thus, even if either reference discussed insect repellency, there would be no motivation for a skilled artisan to combine the two disclosures as suggested by the Examiner. Applicants submit that the Examiner has simply selected similar features from unrelated documents and has combined them using hindsight of the present invention. As such, it is clear that one skilled in the art would not refer to either Marenick or Vroman to derive an insecticidal or insect repellent compound and as such, the combination of Marenick and Vroman does not render claim 1 of the present disclosure obvious.

Furthermore, it is alleged that the applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients or concentrations provides any greater or different level of prior art expectation as claimed. However, on page 3, lines 8-17 of the present disclosure, the surfactant cetrimonium chloride acts synergistically with neem oil in the claimed compositions to result in a pediculicidal composition that results in a virtually 100% kill

rate of both adult lice and eggs. This advantage is unexpected and is nowhere suggested in the prior art cited by the Examiner. Thus, we submit that it is clear that the claimed composition has an unexpected advantage over prior art compositions.

In order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA1974). As is clearly shown, Marenick and Vroman do not disclose a pharmaceutical formulation for use in repelling and/or killing human head lice comprising a solution of Neem Oil and a surfactant, wherein the solution comprises from about 1% w/w to about 1.25% w/w of Neem Oil and from about 0.2% to about 0.3% w/w of surfactant, and the surfactant is cetrimonium chloride. Therefore, Applicant submits that Marenick and Vroman do not render claim 1 of the present invention obvious and accordingly, Applicant respectfully requests that the § 103(a) rejection of claim 1 be withdrawn.

**III. All Dependent Claims Are Allowable Because The Independent Claim From Which They Depend Is Allowable**

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, *Hartness International Inc. v. Simplimatic Engineering Co.*, 819 F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as claim 1 is patentable for the reasons set forth above, it is respectfully submitted that all pending dependent claims are also in condition for allowance.

IV. Conclusion

Having responded to all open issues set forth in the Office Action, it is respectfully submitted that all claims are in condition for allowance.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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